
PROJECT MANAGEMENT

MANAGEMENT OF CDER PROJECT MANAGEMENT COORDINATING COMMITTEE

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PURPOSE

This Guide describes:

- The role and responsibilities of the Project Management Coordinating Committee (PMCC);
 - The procedures to be used for establishing the PMCC and subcommittees;
 - The structure and function of these committees;
 - The procedures to be used in designating members to serve on the committees; and
 - The responsibilities of those designated to serve on the committees.
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BACKGROUND

CDER has formed many committees and working groups to address various project management issues. Coordination of these committees is desirable to ensure effective use of staff resources and to establish and promote consistent project management policy throughout CDER. To achieve these objectives, CDER has established a coordinating committee, the PMCC.

ORGANIZATION

The following descriptions and explanations should be applied on a general basis. There may be some fluctuation in implementation due to workload demands:

- **PMCC**

1. **Chair** - PMCC is chaired by the Senior Center Project Manager, CDER, or the Center Director's designee.
2. **Executive Secretary** - Special Assistant to the Deputy Director of Review Management or the PMCC Chair's designee.
3. **Members** - PMCC representatives are nominated by their respective Offices. Representation will be as follows:
 - 5 Offices of Drug Evaluation (ODEs); one from each Office
 - 2 Office of Epidemiology and Biometrics (OEB)
 - 2 Office of Pharmaceutical Sciences (OPS)
 - 1 Office of Training and Communications (OTCOM)
 - 1 Office of Compliance (OC)
 - 1 Office of Management (OM)
 - 1 Regulatory Policy (RPS)

Each representative will serve for a term of two years except for the initial appointments as follows: representatives from ODEs IV and V, OC, one from OPS, and OM serve a one year term. These offices should designate which representative has a one year term and which has a two year term. Representatives' terms may be extended by mutual agreement between the individual, the respective Office Director, and the committee chair. The terms of the first representatives begin with the first formal meeting in February, 1996.

4. **Other Participants** - With the concurrence of the PMCC Chair, non-voting observers and consultants from other Divisions/Centers or Federal government organizations may be included in the activities of the PMCC to facilitate cross Center and/or agency interactions.

- **Subcommittees (SC)**

1. **Subcommittee Chairs and Co-Chairs** - For each subcommittee, the PMCC and/or the PMCC Chair will select a Chairperson and a Co-Chair, taking into account expertise and interest in the subject matter of the SC, workload, and organizational and management skills. In situations where the Chair and Co-Chair cannot be obtained from within the PMCC membership, the PMCC Chair will nominate candidates for review and

approval by the PMCC.

2. **Membership** - Subcommittee (SC) members should be chosen by the SC Chair and SC Co-Chair with input from the PMCC based upon their qualifications, expertise, and interest in the subject matter of the SC, their workload, and the demands on their time caused by membership on other committees. In general, no person should serve on more than two subcommittees at one time. Membership should be distributed with the goal of achieving broad representation within CDER, provided the individuals selected possess adequate experience and skills to address the needs of the subcommittee. Membership on SCs should normally rotate every two years. When needed, a member's term may be extended with concurrence of the PMCC Chair. The terms will be staggered, as determined by the Chair and Co-Chair.

To facilitate productivity of the subcommittees, the use of smaller, short-term *ad hoc* working groups to address specific issues is encouraged. With PMCC approval, subcommittees may create working groups on specific issues bringing in additional expertise as necessary.

RESPONSIBILITIES

- **PMCC is responsible for:**
 1. Providing advice to the Center/Agency/Department and regulated industry on project management as well as other review management issues that may involve CDER.
 2. Developing strategies for accomplishing long-term and short-term project management goals in CDER including meeting review performance goals.
 3. Coordinating resolution of Project Management issues in CDER.
 4. Serving as liaison between Project Management working level groups and management inside and outside the agency.
 5. Developing and recommending policies and procedures relating to project management.
 6. Documenting Project Management policies through prescribed means (e.g., MAPPs).
 7. Identifying and facilitating the resolution of issues that impede timely completion of regulatory projects, review projects, and other projects. Examples of such issues are:

- Resource allocation recommendations
 - Communications between Center components
 - Priority conflicts
8. Advocating project management, including but not limited to the development and use of project management tools/techniques, and promoting the use of team-based project management, as appropriate, throughout CDER.
 9. Coordinating, facilitating, and monitoring the efforts of the PMCC subcommittees, including:
 - Reviewing subcommittee structure, function, and membership
 - Assigning projects
 - Periodically monitoring subcommittee progress
 - Reviewing and approving subcommittee outputs before transmission to CDER management for clearance
 - Assisting in the resolution of jurisdictional issues that might affect other technical committees (e.g., CMCCC), divisions, offices, or centers
 10. Promoting and coordinating professional development workshops and other intramural and extramural activities related to project management.
 11. Promoting and coordinating with OTCOM training in project management, team-building, and related management approaches for CDER staff.
 12. Promoting experimentation with various project management techniques locally via Pilot programs and promoting successful new approaches (ideas) to the Center.
- **The Chair of the PMCC is responsible for:**
 1. Bringing Center management perspective to policy issues related to project management and resolution of disputes.
 2. Providing overall direction to proceedings of the PMCC.
 3. Assuring that Center level management review and approval is obtained prior to implementation of PMCC or PMCC subcommittee recommendations.
 4. Serving as liaison between PMCC and Center staff and vice-versa.

- **The Executive Secretary of the PMCC is responsible for:**

1. Preparing and distributing the minutes of each PMCC meeting. Minutes shall be E-mailed to members and filed on the common shared drive under X:\PMCC\MEET\YEAR-MONTH-DAY (Example: PMCC\MEET\94-04-25). [Note: For the OGD, the common shared drive is "Y:"]
2. Maintaining a current list of project management-related subcommittees, a brief description of the issue(s) the SC is addressing, and SC members on the common shared drive.
3. Arranging and organizing meetings. Issues to be brought before the PMCC should be directed to the attention of the Executive Secretary who will attempt to schedule them in consultation with the Chair of the PMCC.

- **Members of the PMCC are responsible for:**

1. Attending all PMCC meetings or sending a qualified substitute to represent their area/views.
2. Serving as Chairs or Co-Chairs of subcommittees.
3. Supporting the mission of the PMCC and collaborating with the other members of the PMCC and the Chair in the achievement of PMCC goals.
4. Accurately presenting problems/issues relating to project management.

- **Subcommittees are responsible for:**

1. Serving as a source of advice and assistance to PMCC in responding to CDER staff on matters pertaining to project management, or on matters that are related to their areas of expertise.
2. Completing projects assigned by PMCC within agreed upon time frames.
3. Assuring that proposals for programs, policies, and procedures developed by the subcommittees shall be submitted to PMCC for review and approval prior to broader circulation for comment. [Center management input and concurrence (i.e., ORM, OCD, etc.) will be obtained by the PMCC Chair before programs, policies, or procedures are distributed and implemented.]
4. Establishing working groups, as necessary, to bring in additional expertise on specific issues (with prior approval from the PMCC); working groups should only be created to address a single assignment and should be disbanded upon completion of the assignment.

5. Obtaining PMCC clearance before initiating work not assigned by the PMCC.

- **Chairs of Subcommittees are responsible for:**

1. Reporting to the PMCC at least quarterly to describe the status of all projects in which they are engaged and obtain PMCC input and direction.
2. Developing proposed time frames for completion of projects and forwarding them to PMCC for concurrence. The PMCC may modify projects and priorities as deemed appropriate.
3. Scheduling and conducting meetings to fulfill the subcommittee's objectives. The Co-Chair shall schedule and conduct meetings in the absence of the Chairperson.
4. Preparing an agenda and distributing it to the subcommittee members in advance of each meeting.
5. Assuring preparation of brief minutes of each subcommittee meeting and distributing them to subcommittee members, the PMCC Chair, the PMCC Executive Secretary, and PMCC members via E-Mail and placing the minutes in the common shared drive under X:\PMCC\SC\YEAR-MONTH-DAY. [Note: For OGD, the common shared drive is "Y:".]
6. Ensuring that copies of all supporting documentation related to subcommittee deliberations are distributed to subcommittee members and placed in a file for that specific subcommittee to be maintained by the Executive Secretary for the PMCC.
7. With the assistance of the subcommittee members, creating and maintaining a Task List for the subcommittee describing major tasks the subcommittee is undertaking, projected milestones and completion dates, and the current status of each project. [Normally the Subcommittee Chair or Co-Chair will act as the Project Manager of the subcommittee activities. In cases where subcommittee activities are extensive and the subcommittee Chair feels that additional Project Management assistance is needed, the subcommittee Chair can request PMCC to appoint a Project Manager.]
8. Providing oral reports at least quarterly to the PMCC on the activities of the subcommittee. To prepare the PMCC for these presentations, the subcommittee Chair should provide to the PMCC, at least one week in advance of the meetings, an updated Task List, a summary of achievements since the last report to the PMCC, a projection of activities for the next quarter, and a list of issues for which PMCC input is needed.

9. Obtaining input from PMCC on documents proposing programs, policies, or procedures prior to distribution to individuals or groups outside the Center or to CDER staff other than the PMCC or its subcommittees.
 10. Submitting changes in the membership or objectives of a subcommittee to PMCC for concurrence.
- **Members of Subcommittees are responsible for:**
 1. Representing their discipline's/Division's/Office's views on issues considered by the subcommittee.
 2. Informing management of their participation on the subcommittee and communicating with their discipline, division, or office management (whichever is appropriate) regarding the deliberations of the subcommittee.
 3. Regularly attending the meetings of the subcommittees for which they are designated members. If a member cannot attend a meeting, an alternate may be sent with concurrence of the subcommittee Chair.
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PROCEDURES

- **Meetings** of the PMCC should be convened approximately on a monthly basis.
- **Decision Making** - Deliberations of the PMCC will generally be brought to closure by consensus. However, if consensus cannot be obtained, the PMCC Chair may elect to put the issue to a vote.
- **Voting** - At least 66% of the PMCC members must be present for voting on issues to occur. A simple majority of those in attendance will decide the issue.
- **Minutes** - All PMCC meetings will result in minutes documenting essential points of PMCC meeting deliberations; copies to be made available to PMCC members, the Center Director, Deputy Center Directors, Associate Center Directors, Office Directors, Division Directors, and Project Management staff.
- **Establishment of Subcommittees or Working Groups** - The PMCC has the authority to form new subcommittees or ad hoc working groups. A list of current PMCC subcommittees and working groups is included in Attachment A. Suggestions for new subcommittees or working groups should be forwarded to the PMCC via a PMCC member.

Each suggestion should be accompanied by a statement of the proposed objectives of the subcommittee or working group, the names of persons who might serve as members, the expected frequency of meetings, and the subcommittee's or working

group's expected life (e.g., three months, six months). (PMCC representative to complete Attachment B).

- **Modifications or Disbandment of Subcommittees or Working Groups** - PMCC shall discontinue a subcommittee or working group when it has fulfilled its objectives, or PMCC determines the subcommittee or working group is not fulfilling a necessary function for PMCC.

PMCC shall review annually the list of subcommittees and working groups to determine whether any should be discontinued or the membership or chairpersons changed. If, after discussions with the Chairperson of the subcommittee, PMCC decides that a subcommittee or working group is no longer needed or needs to be changed, PMCC shall issue a notice that the committee will be disbanded or modified.

- **Dispute Resolution** - The PMCC may serve as a forum for dispute resolution for project management issues (i.e., priorities, resources, etc.) arising among different components within the Center. If the PMCC cannot reach agreement on such an issue, it should be brought to the attention of the Center management for resolution.

- **Communications**

1. The activities of PMCC will be communicated to the Center Director, Deputy Center Directors, Associate Center Directors, Office Directors, Division Directors, and Project Management Staff through distribution and electronic filing of the minutes of the PMCC meetings.
2. Committee products shall be distributed for comment, revised as needed, submitted to the appropriate Deputy Center Director (ORM/OPS) or Office Director (directly reporting to the Center Director) for concurrence, and subsequently issued. If the committee product has cross-Center impact, it shall also be submitted to the Center Director or designee for review and approval prior to issuance.
3. CDER staff may raise issues for consideration by the PMCC through their respective supervisors or directly via Subcommittee Chairs, Co-Chairs, PMCC members, the PMCC Executive Secretary and/or the Senior Center Project Manager (PMCC Chair).

EFFECTIVE DATE

This guide is effective upon date of publication.

Attachment A

PMCC SUBCOMMITTEES (SC) AND WORKING GROUPS (WG)

<u>Committee</u>	<u>Type</u>	<u>Status</u>
Regulatory	SC	Active
Communications [coordinate with OTCOM]	SC	Active
Training [coordinate with OTCOM]	SC	Active
Certification [coordinate with OTCOM]	SC	Active
Standardized Letters	SC	Active
P. M. Standards	SC	Activating
Priority Reviews	SC	Activating
Consult Issues	SC	Activating
Program Technical Enhancements	SC	Activating
Forms Harmonization	WG	Active
IND Reform Issues	WG	Active

Attachment B

**RECOMMENDATION FOR THE CREATION OF
A PMCC SUBCOMMITTEE OR WORKING GROUP**

1. **Name of Committee:**

2. **Objectives:**

3. **Composition:**

Chairperson:

Co-Chair:

Membership:

4. **Meeting Frequency:**

5. **Completion Date:**

Concur: _____

Non-Concur: _____

Chairperson, PMCC

Date

Concur: _____

Non-Concur: _____

Co-Chairperson, PMCC

Date